Remarks

Claims 4-28 are pending in this application. By way of this amendment, claims 4, 10, 17-18, 20-24, and 26-28 have been amended and claims 15, 19, and 25 have been canceled. Accordingly, claims 4-14, 16-18, 20-24, and 26-28 are currently pending in the subject application. Favorable consideration of the pending claims is earnestly solicited.

The applicants are submitting a substitute specification in order to include line-numbering which was inadvertently omitted on the specification filed September 22, 2003, and to correct typographical errors and errors in the translation of the specification. Also submitted is a marked-up version of the specification showing the corrections to the typographical errors on page 1, lines 21 and 29 and correction of the errors in the translation on page 2, line 5 and page 2, line 30. The original translation failed to translate the German term "wolfram" into the English term "tungsten". In addition, the original translation incorrectly inserted the terms "as well as additives of titanium and beryllium" and "as well as an iron additive". A more accurate translation is "and titanium and beryllium for the balance" and "and iron for the balance", respectively. Submitted herewith for the Examiner's consideration is an unsigned expert Declaration under 37 C.F.R. §1.132 by Axel Winkel. As described in Axel Winkel's Declaration, these amendments to the specification provide a more accurate translation of the pertinent language of the original specification which was in German.

The applicants' amendment filed September 25, 2003 is objected to under 35 U.S.C. §132. The specification as originally filed taught "the materials are classified under the ISO 5832/7..." and the amendment of September 22, 2003 added the composition of the ISO 5832/7 material. Attached to this Amendment as Appendix A is a copy of a two-page published ISO International Standard for the ISO 5832/7 material which was published by the International Organization for Standardization in 1994. Based on the material chemical composition defined in this published ISO International Standard, the applicants assert the Amendment of September 22, 2003 did not introduce any new matter. Accordingly, the applicants respectfully request reconsideration and removal of the objection to the specification.

Claim 15 has been rejected under 35 U.S.C. §112, first paragraph. In order to expedite the prosecution of the subject application, claim 15 has been canceled. This amendment should not be taken as an indication of the applicant's agreement with or acquiescence in the rejection of claim 15. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection of

claim 15 under 35 U.S.C. §112.

Claims 17-28 have been rejected under 35 U.S.C. §112, second paragraph, and under 35 U.S.C. §101. In order to expedite the prosecution of the subject application, claims 17 and 23 have been amended to incorporate the limitation "inserting a stent into a cavity of a patient" such that claims 17 and 23 are now directed to a method of treating a patient comprising inserting a stent into a cavity of a patient. Claims 22 and 28 have been amended to add the limitation "wherein inserting a stent into a cavity of a patient comprises inserting the stent into a cardiovascular vessel of the patient." Claims 18, 21, 24, and 27 have been amended to be consistent with the amendments to claims 17 and 23. These amendments should not be taken as an indication of the applicant's agreement with or acquiescence in the rejection of claims 17-28. Claims 19 and 25 have been canceled. Support for the amendments can be found at least at page 2, lines 8-15. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection of claims 17-28 under 35 U.S.C. §112 and under 35 U.S.C. §101.

Claims 4-28 have been rejected under 35 U.S.C. §112, second paragraph. Claims 20, 21, 22, 26, 27 and 28 have been amended to correct the typographical error pointed out by the Examiner, by replacing "The device according to" with "The method according to." Claims 4 and 17 have been amended to replace "wolfram" with "tungsten" and to replace "titanium additives; and beryllium additives" with "and titanium and beryllium for the balance" and claims 10 and 23 have been amended to replace "an iron additive" with "iron for the balance". Support for these amendments to claims 4, 10, 17, and 23 can be found in the specification which has been amended at page 2, line 5, to replace "as well as additives of titanium and beryllium" with "and titanium and beryllium for the balance" and amended at page 2, line 30, to replace "as well as an iron additive" with "and iron for the balance". Support for these amendments can be found in the original specification in German, in conjunction with the expert Declaration of Axel Winkel which is discussed above. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection of claims 4-28 under 35 U.S.C. §112.

Claims 4 - 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fariabi (U.S. Patent No. 5,636,641). The Office Action states that Fariabi teaches a cobalt-nickel-chromium alloy having a composition that overlaps the alloy composition recited in the instant claims (column 2, lines 22 to 38) and that Fariabi teaches that the disclosed alloy is used to make elongated intra

vascular bodies such as a guidewire, a stent or the like (column 2, lines 9 to 11) as recited in the instant claims. However, the alloy taught in the Fariabi reference, at column 2, lines 22-38 also includes up to 3% manganese. In contrast, the subject invention as claimed in claims 4-14, 16-18, 20-24, and 26-28 does not incorporate an alloy including up to 3% manganese. In addition, the alloy taught by the Fariabi reference, at column 2, lines 23-38, does not include titanium and beryllium for the balance, a does the subject invention as claimed in claims 4-9, 17-18, and 20-22. Also, the alloy taught by the Fariabi reference, at column 2, lines 23-38, includes up to 20% tungsten. In contrast, the subject invention as claimed in claims 10-14, 23-24, and 26-28 does not incorporate an alloy including up to 20% tungsten. Accordingly, the alloy taught by the Fariabi reference does not have a composition that overlaps the alloy composition recited in claims 4-14, 16-18, 20-24, and 26-28 of the subject application. Therefore, a *prima facie* case of obviousness has not been presented.

With respect to claims 18 and 24, the Fabriabi reference does not teach or suggest a method of treating a patient comprising inserting a stent into a cavity of a patient under nuclear spin tomography magnetic resonance imaging.

Therefore, the Fariabi reference does not teach or suggest the subject invention as claimed in claims 4-14, 16-18, 20-24, and 26-28 of the subject application. Accordingly, applicants respectfully request reconsideration and withdrawal of the rejection of claims 4-28 under U.S.C. §103.

In view of the foregoing remarks and the amendment above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

James S. Parker
Patent Attorney
Registration No. 40,119
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

JSP/sjk
Attachment: 1. Petition and Fee for Extension of Time
2. Declaration under 37 C.F.R. §1.132 by Dr. Axel Winkel

DESCRIPTION

DEVICES FOR NUCLEAR SPIN TOMOGRAPHY MAGNETIC RESONANCE IMAGING (MRI)

Cross-Reference to Related Application

This application claims priority to German Application No. 10108581.8, filed February 22, 2001.

Background of Invention

In today's interventional nuclear spin tomography MRI, it is desirable to utilize materials of a certain elasticity, such as is used in springs, in biopsy and other automated needles, and cardiovascular or other cavity stents. Titanium based materials exhibiting low field distortion, or image artifacts, in nuclear spin tomography, are in part too brittle and have insufficient elasticity. Filigree structures imaging isn't optimal either.

Brief Summary of the Invention

The subject invention pertains to devices for use in nuclear spin tomography magnetic resonance imaging (MRI). The subject devices incorporate materials having desirable properties, such as elasticity. In a specific embodiment, the subject device can incorporate_stainless steels of a cobalt-nickel chrome-based alloy. The subject invention relates to devices for nuclear spin tomography MRI, such as springs, automated needles, stents, cardiovascular stents, torsion springs, coil springs, membrances, and guide wires.

Detailed Description of the Invention

The subject invention pertains to devices for use in nuclear spin tomography magnetic resonance imaging (MRI). The subject devices incorporate materials having desirable properties, such as elasticity. In a specific embodiment, the subject device can incorporate_stainless steels of a cobalt-nickel chrome-based alloy. The subject invention

relates to devices for nuclear spin tomography MRI, such as springs, automated needles, stents, cardiovascular stents, torsion springs, coil springs, membrances, and guide wires.

The first alloy on a CoNiCr base consists of 42 to 48% cobalt by weight, 19 to 25% nickel by weight, 16 to 20% chromium by weight, 2 – 6% molybdenum by weight, 2 – 6% tungsten~~wolfram~~ by weight, 2.5 to 7.5% iron by weight,~~ as well as additives of~~ and titanium and beryllium for the balance. The material can be further hardened. It is breakproof and can be utilized for highly challenged small dimensional springs, which must also be antimagnetic.

The material is highly suitable for springs utilized in measuring and display instruments of all kinds, including torsion and coil springs, membranes and other springs requiring high resistance accuracy. It is equally suitable for stents. For this application it is drawn into tiny tubes and subsequently cut into stents. Stents are metallic spring elements that are inserted into cavities in the human body, e.g., cardiovascular vessels, in order to prevent them from closing. The stents are introduced into the body with the help of catheters that are in turn guided in by guide wires. The core of the guide wire frequently consists of a long spring wire and the material cited here is ideally suited for its manufacture.

The material exhibits a high degree of corrosion resistance. Its superior cold fabrication properties in conjunction with good temperability produces an exceptionally durable, fatigue-free substance, that in tempered condition offers very attractive long-term stability values in situations with both high and low metal fatigue windows. Futhermore, the alloy can be utilized in a permanent application up to the middle temperature range, i.e., from -50°C to 350°C. The material has an elasticity modulus of 219.5 to 234.4 kN/mm^2. Due its relative permeability of <1.005μ it cannot become magnetized in the nuclear spin tomography MRI or nuclear magnetic resonance unit. The material is biocompatible and can be used for implants in the human body.

Another material consists of 39 to 41% cobalt by weight, 15 to 18% nickel by weight, 19 to 21% chromium by weight, 6.5 to 7.5% molybdenum by weight, <0.15% carbon, <1.2% silicon by weight, <0.01% beryllium by weight, <0.015% sulfur by weight, <0.015% phosphorous by weight,~~ as well as an~~ and iron for the balance~~additive~~.

The mechanical properties are similar to those of the first named materials, wherein the elasticity modulus (Youngs modulus) is at 212 kN/mm^2.

The materials are classified under the ISO 5832/7, AFNOR NF S 90-403, ASTM F1058-91 standards, where ISO 5832/7 is a material, as known in the art, having a chemical composition of 39 to 42% (m/m) cobalt, 18.5 to 21.5% (m/m) chromium, 14 to 18% (m/m) nickel, 6.5 to 8% (m/m) molybdenum, 1 to 2.5% (m/m) manganese, up to 1% (m/m) silicon, up to 0.15% (m/m) carbon, up to 0.015% (m/m) phosphorous, up to 0.015% (m/m) sulfur, up to 0.001% (m/m) beryllium, and iron for the balance.

Abstract

The subject invention relates to a material for magnetic resonance imaging, and apparatus incorporating such material. The subject material can comprise cobalt, nickel, and chromium and can be used in nuclear spin tomography MRI. In specific embodiments, the subject material can be used in stents, mechanical springs, and guide wires.

Appendix A

INTERNATIONAL STANDARD © ISO ISO 5832-7:1994(E)

Implants for surgery — Metallic materials —

Part 7:
Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy for use in the manufacture of surgical implants.

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size.*

ISO 4967:1979, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams.*

ISO 6892:1984, *Metallic materials — Tensile testing.*

3 Chemical composition

The heat analysis of the alloy when determined as specified in clause 6 shall comply with the chemical composition specified in table 1. The analysis of samples taken from products manufactured from the alloy shall also comply with table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (*m/m*)
Cobalt	39 to 42
Chromium	18,5 to 21,5
Nickel	14 to 18
Molybdenum	6,5 to 8
Manganese	1 to 2,5
Silicon	1 max.
Carbon	0,15 max.
Phosphorus	0,015 max.
Sulfur	0,015 max.
Beryllium	0,001 max.
Iron	Balance

4 Microstructure

4.1 Grain size

The microscopic structure shall be uniform. The grain size, determined as specified in clause 6, shall be no coarser than grain size No. 5.

4.2 Inclusion content

The non-metallic inclusion content of the alloy, determined as specified in clause 6, shall not exceed the limits given in table 2.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content thin[1)]
A — Sulfides	1
B — Aluminates	3
C — Silicates	1
D — Oxides, globular	3
1) There shall be no thick inclusions.	

5 Mechanical properties

The mechanical properties, determined as specified in clause 6, shall be in accordance with the requirements of table 3.

6 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5832 shall be those given in table 4.

Table 3 — Mechanical properties

Condition	Tensile strength min. MPa	Proof stress of non-proportional elongation min. MPa	Percentage elongation min. %
Annealed	950	450	65
30 % cold-worked	1 450	1 300	8
Spring temper[1)]	1 650	1 400	1
1) for specific applications.			

Table 4 — Test methods

Requirement	Relevant clause or subclause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Inclusion content	4.2	ISO 4967
Grain size	4.1	ISO 643
Mechanical properties Tensile strength Percentage elongation Proof stress of non-proportional elongation	5	ISO 6892